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LORI L. KERBER
INCYTE CORPORATION
3160 PORTER DRIVE
PALO ALTO, CALIFORNIA 94304

In re Application of	:
Tang et al.	:Petition to Review Lack of Unity
Serial No: 09/700,590	:Under 37 C.F.R. 1.144
Filed: 16 April 2001	:
Attorney Docket No: PF-0526 USN	:

This is in response to applicant's petition under 37 CFR 1.144, filed 29 March 2004, requesting review of the Examiner's lack of unity requirement mailed 25 July 2001.

BACKGROUND

This application is a U.S. national stage application properly filed under 35 USC 371.

The Examiner instituted a lack of unity requirement of claims 1-20 into 8 groups and required a selection of a single sequence for examination in an Office action which was subsequently made final. In particular, the following lack of unity between Group II and Group I is at issue:

> Group I, claims 1,2, 15, drawn to polypeptide having SEQ ID NO:101.
>
> Group II, claims 3, 6, 9-14, drawn to polynucleotide encoding SEQ ID NO:101 or having SEQ ID NO 22.

In the response dated 23 December 2003 to the lack of unity requirement Applicant elected, with traverse, Group II and polynucleotides encoding polypeptide SEQ ID NO:101 including the nucleotide SEQ ID NO:22. The examiner then considered the traversal, found it not persuasive and made the lack of unity holding final.

RELEVANT AUTHORITY

An international or a national stage application are considered to have unity of invention where there exists a "special technical feature" that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See PCT Rule 13.2; 37 CFR 1.475(a), (b)(1) and (2).

PCT Rule 13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

PCT Administrative Instructions, Annex B, Part 2, Example 17 states:

> *Claim 1: Protein X*
> *Claim 2: DNA sequence encoding protein X.*

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity of invention between claims 1 and 2 is accepted.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims.

DISCUSSION

Applicant's petition and the file record have been carefully considered.

Applicants are correct that the above-identified application is a national stage application submitted under 35 U.S.C. 371 to which "unity of invention", and not U.S. restriction practice is applicable. See MPEP section 1893.03(d). The lack of unity between independent polypeptide claims of Group I and independent polynucleotide claims of Group II is therefore at issue.

Independent claim 21 (corresponding to Group I) and claim 31 (corresponding to Group II) are reproduced below:

> 21. An isolated polypeptide selected from the group consisting of:
> a) a polypeptide comprising the amino acid sequence of SEQ ID NO:22,
> b) a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:22,

c) a biologically active fragment of a polypeptide having the amino acid sequence of SEQ ID NO:22, and
d) an immunologically active fragment of a polypeptide having the amino acid sequence of SEQ ID NO:22, wherein said immunologically active fragment generates an antibody that specifically binds to SEQ ID NO:22.

31. An isolated polynucleotide selected from the group consisting of:
a) a polynucleotide comprising the polynucleotide sequence of SEQ ID NO:101,
b) a polynucleotide comprising a naturally occurring polynucleotide sequence at least 90% identical to the polynucleotide sequence of SEQ ID NO:101,
c) a polynucleotide complementary to a polynucleotide of a),
d) a polynucleotide complementary to a polynucleotide of b), and
e) an RNA equivalent of a)-d).

Applicant argues that in accordance with PCT Administrative Instructions, Example 17, the claims of Group I and Group II should possess unity of invention. Applicants have argued and added emphasis to the following sentence of Example 17:

The protein and the DNA sequence exhibit corresponding special technical features.

Applicants appear to be arguing that this sentence is a conclusion directed at any particular combination of DNA and protein inventions. This is not persuasive. This sentence is understood to present background facts relating to this particular example which specifies that in these claims, the DNA encodes the protein, the DNA and protein make a contribution over the prior art. In the inventions of Example 17, the groups share a technical feature which makes a contribution over the prior art, therefore, unity is accepted.

Applicant's argument is misplaced since PCT Rule 13.2 and Example 17 specifically indicates that unity of invention between the protein and its corresponding encoding nucleotide sequence requires that the protein and the DNA sequence exhibit corresponding special technical features, i.e., make a contribution over the prior art.

The inventions under consideration here do not fit into the pattern of Example 17 and therefore are not considered to have unity of invention for the following reasons. It is first noted that the representative claims 21 and 31 above are drawn to a genus of nucleotides encoding a genus of polypeptides and not a genus of nucleotides encoding a single protein as in Example 17. Accordingly, in the first instance, unity of invention pursuant to Example 17 may not be applicable.

With regard to the isolated polynucleotides of claim 31, it is first noted these polynucleotides lack the functional limitation required by Example 17 since the polynucleotides of claim 31 are not required to encode any polypeptide. Claim 31(b) defines the polynucleotide only in terms of partial structure and reads upon polynucleotides which are at least 90% identical to SEQ ID NO:101. A polynucleotide containing a stop codon truncating the open reading frame or the presence of a splice site which results in an open reading frame shift would fit into the required structural limitation but it would not encode the polypeptide having at least 90% identity to SEQ

ID NO:22. The complementary sequences encompassed by parts (c) and (d) of claim 31 are non-coding strands of any length. Transcription and translation of a non-coding strand would not result in the polypeptide having SEQ ID No 22. Within the large numbers of polynucleotides encompassed by Claim 31, many which could encode a polypeptide would not encode the polypeptides of Group I. For these reasons, Groups I and II lack a same or corresponding technical feature, as required by PCT Rule 13.2. The protein invention and the polynucleotide invention lack a one-to-one correspondence.

Even if the polynucleotides and polypeptides shared a same or corresponding technical feature, they do not both make a contribution over the prior art. The attached sequence alignment shows a polypeptide sequence which is 99.7 % identical to SEQ ID NO 22. See the alignment of SEQ ID NO 22 with Accession Number Y12059, submitted to Genbank on 2 May 1998, which is prior to the earliest claimed priority date of 29 May 1998. Claim 21, part (b) encompasses polypeptides which are 90% identical to SEQ ID No 22.

For these reasons, the lack of unity of invention between the polypeptide and the polynucleotide is maintained.

DECISION

Applicant's petition to withdraw the lack of unity requirement between Groups I and II under 37 CFR 1.144 is **DENIED** for the reasons set forth above.

The application will be forwarded to the Examiner for consideration of the Appeal Brief filed on 8 April 2004

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600.

Jasemine Chambers
Director, Technology Center 1600.

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HSHUNKI
LOCUS       HSHUNKI                 3149 bp    mRNA    linear   PRI 02-MAY-1998
DEFINITION  H.sapiens HUNKI mRNA.
ACCESSION   Y12059
VERSION     Y12059.1  GI:3115203
KEYWORDS    HUNKI gene.
SOURCE      Homo sapiens.
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
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REFERENCE   1  (bases 1 to 3149)
  AUTHORS   Weber,B.
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 3149)
  AUTHORS   Weber,B.
  TITLE     Direct Submission
  JOURNAL   Submitted (24-MAR-1997) B. Weber, Labor Paediatrische
            Molekularbiologie, Universitaetsklinikum Charite, Ziegelstr. 5-9,
            10098 Berlin, FRG
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BASE COUNT      818 a    946 c    788 g    597 t
ORIGIN

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Percent Similarity:       99.71%         Conservative:    0
Best Local Similarity:    99.71%         Mismatches:      2
Query Match:              98.46%         Indels:          2
DB:                       9              Gaps:            0

US-09-700-590A-22 (1-688) x HSHUNKI (1-3149)

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Qy     161 IleAsnGluLeuProThrGluGluThrGluIleMetIleValGlnAlaLysGlyArgGly 180
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Qy     201 GlnAlaSerThrProProGlnThrGlnThrProGlnProAsnProProProValGlnAla 220
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Qy     241 ValValProProGlnProLeuGlnThrProProProValProProGlnProGlnProPro 260
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VERSION     AF386649.1  GI:16589002
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REFERENCE   1  (bases 1 to 5198)
  AUTHORS   French,C.A., Miyoshi,I., Aster,J.C., Kubonishi,I., Kroll,T.G., Dal
            Cin,P., Vargas,S.O., Perez-Atayde,A.R. and Fletcher,J.A.
  TITLE     BRD4 bromodomain gene rearrangement in aggressive carcinoma with
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  JOURNAL   Am. J. Pathol. 159 (6), 1987-1992 (2001)
  MEDLINE   21590020
   PUBMED   11733348
REFERENCE   2  (bases 1 to 5198)
  AUTHORS   French,C.A. and Fletcher,J.A.
  TITLE     Direct Submission
  JOURNAL   Submitted (28-MAY-2001) Pathology, Brigham and Women's Hospital, 75
            Francis St., Boston, MA 02115, USA
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ORIGIN

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Score:                    3583.00         Matches:         686
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Query Match:              98.46%          Indels:          2
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US-09-700-590A-22 (1-688) x AF386649 (1-5198)

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1: Y12059. H.sapiens HUNKI m...[gi:3115203] Links

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ACCESSION   Y12059
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            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1
  AUTHORS   Weber,B.
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 3149)
  AUTHORS   Weber,B.
  TITLE     Direct Submission
  JOURNAL   Submitted (24-MAR-1997) B. Weber, Labor Paediatrische
            Molekularbiologie, Universitaetsklinikum Charite, Ziegelstr. 5-9,
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